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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,984	07/24/2003	Jungwon Shin	INL-059	1711
22832	7590	09/26/2006	EXAMINER	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP STATE STREET FINANCIAL CENTER ONE LINCOLN STREET BOSTON, MA 02111-2950			NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,984

Applicant(s)

SHIN ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/24/2003</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: IDS of 10/31/2003 and IDS of 12/15/2003.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 5-7, 9-22, 24-26, 28-42, 44, 45, and 47-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Mansouri et al. (US 2003/0062262 A1) ("Mansouri").

Addressing claim 1, Mansouri discloses a solution for the calibration of an oxygen sensor, the solution comprising

a selected concentration of choline; and a known oxygen content. See Figures 1 and 2 and paragraphs [0055] and [0064].

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

Addressing claims 3, 5-7, 9, 24-26, 28, 39-42, 44 for the additional limitations of these claims see [0064].

Addressing claims 10-18, 29-37, and 47-55, for the additional limitations of these claims see [0064] and [0067].

Addressing claim 19, Mansouri discloses a container (16) of calibration solution for calibrating an electrochemical sensor (abstract and [0059]), the container of calibration solution comprising

the calibration solution ([0059]), comprising

a selected concentration of choline ([0064]); and
a known oxygen content ([0064]).

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

Addressing claims 20 and 21, for the additional limitations of these claims see [0073].

Addressing claim 22, for the additional limitation of this claim see [0064].

Addressing claim 38, Mansouri discloses a solution having a known oxygen

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content and an amount of choline. See Figures 1 and 2 and paragraphs [0055] and [0064].

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the. However, this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound.

Addressing claim 45 (second claim 44), for the additional limitations of this claim see [0064].

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 2, 8, 27, and 43 are rejected under 35 U.S.C. 103(a) as being obvious over Mansouri et al. (US 2003/0062262 A1) ("Mansouri").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Addressing claim 2, Mansouri discloses a solution for the calibration of an oxygen sensor, the solution comprising

a selected concentration of choline; and a known oxygen content. See Figures 1 and 2 and paragraphs [0055] and [0064].

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen

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content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

Mansouri does not mention the rate of loss of oxygen content in the solution, particularly whether it is in the range of about 0.5 mmHg/month to about 5.0 Hg/month. It should be first noted, though, that Applicant's disclosure seems to suggest that 20 mM choline chloride will reduce the rate of oxygen loss to within the claimed range. See page 19, line 18 – page 20, line 20. In any event, Mansouri clearly seeks a very low rate of oxygen loss as the calibration "solutions are packaged in a zero head-space, flexible gas-impervious container." See [0073]. A rate loss in the claimed range is clearly desirable as the $pO_2 = 180$ mmHg, so a loss of 5.0mm Hg/month is a loss of over 2%/ month, enough to affect measurement accuracy.

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Addressing claim 8, Mansouri discloses a solution for the calibration of an oxygen sensor, the solution comprising

a selected concentration of choline; and a known oxygen content. See Figures 1 and 2 and paragraphs [0055] and [0064].

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

The oxygen content of the calibration solution in Mansouri comprises 180 mmHg. See [0064]. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide at least one other calibration solution with oxygen content other than 180 mmHg that would be best for calibrating the sensor response for the expected range of oxygen content in sample. For example, if the expected oxygen content in samples will be 80-120 mmHg oxygen, clearly a calibration solution with 100mmHg oxygen is more appropriate for one point calibration than one with 180 mmHg. Similarly, for two point calibration, two calibration solutions, one with calibrant

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concentration near the low end of the expected concentration range and another calibration solution with a calibrant concentration near the high end of the expected concentration range should be used.

Addressing claim 27, Mansouri discloses a container (16) of calibration solution for calibrating an electrochemical sensor (abstract and [0059]), the container of calibration solution comprising

the calibration solution ([0059]), comprising

a selected concentration of choline ([0064]); and

a known oxygen content ([0064]).

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

The oxygen content of the calibration solution in Mansouri comprises 180 mmHg. See [0064]. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide at least one other calibration solution with oxygen content other than 180 mmHg that would be best for calibrating the sensor response for the expected range of oxygen content in sample. For example, if the expected oxygen content in samples will be 80-120 mmHg oxygen, clearly a calibration solution with 100 mmHg oxygen is more appropriate for one point calibration than one with 180 mmHg. Similarly, for two point calibration, two calibration solutions, one with calibrant concentration near the low end of the expected concentration range and another calibration solution with a calibrant concentration near the high end of the expected concentration range should be used.

Addressing claim 43, Mansouri discloses a solution having a known oxygen content and an amount of choline. See Figures 1 and 2 and paragraphs [0055] and [0064].

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the. However, this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. The oxygen content of the calibration solution in Mansouri comprises 180 mmHg. See [0064]. However, it

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would have been obvious to one with ordinary skill in the art at the time of the invention to provide at least one other calibration solution with oxygen content other than 180 mmHg that would be best for calibrating the sensor response for the expected range of oxygen content in sample. For example, if the expected oxygen content in samples will be 80-120 mmHg oxygen, clearly a calibration solution with 100mmHg oxygen is more appropriate for one point calibration than one with 180 mmHg. Similarly, for two point calibration, two calibration solutions, one with calibrant concentration near the low end of the expected concentration range and another calibration solution with a calibrant concentration near the high end of the expected concentration range should be used.

7. Claims 4, 23, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansouri et al. (US 2003/0062262 A1) ("Mansouri") in view of Nakanishi et al. (US 4,245,050) ("Nakanishi").

Addressing claim 4, Mansouri discloses a solution¹ for the calibration of an oxygen sensor, the solution comprising

a selected concentration of choline; and a known oxygen content. See Figures 1 and 2 and paragraphs [0055] and [0064].

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

Also, the choline is in the form of choline chloride compound. Mansouri does not mention any of the claimed forms of choline. However, since the choline is presumably added to calibrate a choline sensor, likely one with choline oxidase, at least choline bicarbonate, choline citrate, choline ascorbate are obvious variants of choline because as shown by Nakanishi these known to be interchangeable substrates for choline oxidase. See col. 1:26-34 and col. 2:59-63.

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Addressing claim 23, Mansouri discloses a container (16) of calibration solution for calibrating an electrochemical sensor (abstract and [0059]), the container of calibration solution comprising

the calibration solution ([0059]), comprising

a selected concentration of choline ([0064]); and

a known oxygen content ([0064]).

Mansouri does not mention that the selected concentration of choline is sufficient to reduce a rate of loss of oxygen content in the solution and that the known oxygen content in the solution is sufficient for calibration of the oxygen sensor. As for the selected concentration of choline being sufficient to reduce a rate of loss of oxygen content in the solution this is an inherent property of 20 mM choline chloride. See Applicant's specification page 3, line 14 – page 4, line 4, which is only cited to establish a property of a compound. As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is implicit in Mansouri since the calibration solution is for calibrating an array of sensors including an oxygen sensor (70). See paragraph [0082].

Also, the choline is in the form of choline chloride compound. Mansoui does not mention any of the claimed forms of choline. However, since the choline is presumably added to calibrate a choline sensor, likely one with choline oxidase, at least choline bicarbonate, choline citrate, choline ascorbate are obvious variants of choline because as shown by Nakanishi these known to be interchangeable substrates for choline oxidase. See col. 1:26-34 and col. 2:59-63.

Addressing claim 46, Mansouri discloses a solution having a known oxygen content and an amount of choline. See Figures 1 and 2 and paragraphs [0055] and [0064].

The choline in Mansouri is in the form of choline chloride compound. Mansouri does not mention any of the claimed forms of choline. However, since the choline is presumably added to calibrate a choline sensor, likely one with choline oxidase, at least choline bicarbonate, choline citrate, choline ascorbate are obvious variants of choline because as shown by Nakanishi these known to be interchangeable substrates for choline oxidase. See col. 1:26-34 and col. 2:59-63.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

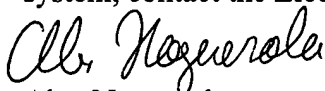
9. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There are two claims labeled "44."

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Nogueroles
Primary Examiner
AU 1753

September 18, 2006